



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration  
New England District

3629d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

**October 7, 2002**

**WARNING LETTER**

**NWE-01-03W**

**FEDERAL EXPRESS**

Anthony Castiglione, General Manager  
Tony & Sons Seafood, LLC  
639 Main Street  
Oakville, Connecticut 06779

Dear Mr. Castiglione:

We inspected your firm, located at 639 Main Street, Oakville, Connecticut, on September 5 - 10, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR 123). These deviations cause your scombrototoxin species, vacuum packaged cold smoked salmon and pasteurized crabmeat processed by your firm to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 342(a)(4)]. You can find the Act and the Seafood HACCP regulations though links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR §123.6(b). However your firm does not have HACCP plans for:
  - a. Vacuum packaged raw fish to control the food safety hazard of *Clostridium botulinum*, and
  - b. Pasteurized canned crabmeat to control the food safety hazard of pathogens.
2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). See also 21 CFR 123.6(c)(7). However, your firm did

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Oakville, CT  
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not record monitoring observations at the receiving critical control point to control histamines listed in your HACCP plan for scombrototoxin species.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR §110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



Gail T. Costello  
District Director  
New England District

cc: Patricia C. Castigliego, President  
Tony & Sons Seafood, LLC  
639 Main Street  
Oakville, Connecticut 06779